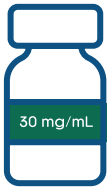
Pr CRYSVITA®
burosumab injection
Solution for Subcutaneous Injection
10, 20, 30 mg/mL

PrCRYSVITA® XLH AND TIO DOSING GUIDE

CRYSVITA is available in three strengths and is administered via subcutaneous injection by a health professional.

10 mg/mL

20 mg/mL



30 mg/mL

DOSING CONSIDERATIONS[1]

- Discontinue oral phosphate and active vitamin D analogues ≥1 week prior to treatment initiation. Non-active vitamin D supplementation may be continued.
- Fasting serum phosphorus concentration should be below the reference range for age prior to treatment initiation.

CRYSVITA (burosumab injection) is indicated for the treatment of:

- X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- FGF23-related hypophosphatemia in tumour-induced osteomalacia (TIO) associated with tumours that cannot be curatively resected or localized in adult patients.

TIO=tumour-induced osteomalacia; XLH=X-linked hypophosphatemia.

Kyowa KIRIN

ADMINISTER ONCE EVERY TWO WEEKS BY SUBCUTANEOUS INJECTION[1]

Dosing in patients 6 months to 1 year and adolescents (aged 13 to 17) was derived using modelling and simulation of adult and pediatric (aged 1 to 12 years) PK and PD data.

FOR PATIENTS AGED 6 MONTHS TO <1 YEAR (with body weight ≥6 kg):

RECOMMENDED STARTING DOSE:

Round down to the **nearest 1 mg**
Minimum recommended initial dose: 5 mg

0.8 mg/kg of body weight

FOR PATIENTS AGED 1 TO 18 YEARS:

RECOMMENDED STARTING DOSE:

Round to the **nearest 10 mg**
Minimum recommended starting dose: 10 mg, up to a maximum dose of 90 mg

0.8 mg/kg of body weight

Check patient weight periodically to ensure proper total dose for patient weight is being administered.

MONITORING FOR DOSE ADJUSTMENTS:

Measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate.

IF SERUM PHOSPHORUS IS WITHIN THE LOWER LIMIT OF THE REFERENCE RANGE FOR AGE:

Continue treatment with the same dose.

IF SERUM PHOSPHORUS IS BELOW THE REFERENCE RANGE FOR AGE:

Increase dose stepwise in intervals of 0.4 mg/kg.

Maximum in patients aged 6 months to <1 year: 1.2 mg/kg

- The calculated dose should be rounded to the nearest 1 mg.

Maximum in patients aged 1 to 18 years: 2 mg/kg

- The calculated dose should be rounded to the nearest 10 mg with a maximum dose of 90 mg.

Reassess fasting serum phosphorus level **4 weeks after dose adjustment**. Do not adjust CRYSVITA dose more frequently than every 4 weeks.

IF SERUM PHOSPHORUS IS ABOVE THE REFERENCE RANGE FOR AGE:

Withhold the next dose and reassess the serum phosphorus level in 4 weeks. The patient must have serum phosphorus below the reference range for age to reinitiate CRYSVITA.

Once serum phosphorus is below the reference range for age, **restart CRYSVITA at half the dose level previously administered**.

Gradually increase the dose according to the instructions above if the level is below the reference range for age upon reassessment 4 weeks later.

PD=pharmacodynamic; PK=pharmacokinetic; XLH=X-linked hypophosphatemia.
* See CRYSVITA Product Monograph for complete dosing and administration instructions.

ADMINISTER ONCE EVERY FOUR WEEKS BY SUBCUTANEOUS INJECTION[1]

FOR PATIENTS AGED 18 YEARS AND OLDER:

RECOMMENDED INITIAL DOSE:

Round to the nearest 10 mg up to a maximum dose of 90 mg.

1 mg/kg of body weight

MAXIMUM DOSE:

CRYSVITA should not be administered at doses greater than 1 mg/kg in adults with XLH.

90 mg

Recalculate dose if there are changes in patient weight of ±10%.

MONITORING FOR DOSE ADJUSTMENTS:

Measure fasting serum phosphorus on a monthly basis for the first 3 months of treatment, beginning 2 weeks post-dose, and thereafter as appropriate.

IF SERUM PHOSPHORUS IS WITHIN THE NORMAL RANGE:

Continue treatment with the same dose.

IF SERUM PHOSPHORUS IS ABOVE THE NORMAL RANGE:

Withhold the next dose and reassess the serum phosphorus level in 4 weeks. The patient must have serum phosphorus below the normal range to be able to reinitiate CRYSVITA.

Once serum phosphorus is below the normal range, **restart CRYSVITA at half the previous recommended initial dose** up to a maximum dose of 40 mg every 4 weeks.

Reassess serum phosphorus **2 weeks after any change in dose**. Do not adjust CRYSVITA dose more frequently than every 4 weeks.

XLH=X-linked hypophosphatemia.
* See CRYSVITA Product Monograph for complete dosing and administration instructions.

ADMINISTER BY SUBCUTANEOUS INJECTION ACCORDING TO THE FOLLOWING INSTRUCTIONS[1]

Treatment should be initiated and monitored by a health professional experienced in the management of patients with metabolic bone diseases.

FOR PATIENTS AGED 18 YEARS AND OLDER:

RECOMMENDED STARTING DOSE:

Round to the nearest 10 mg
Maximum dose: 2 mg/kg every 2 weeks

0.5 mg/kg of body weight **(every 4 weeks)**

MONITORING FOR DOSE ADJUSTMENTS

After initiating CRYSVITA, assess fasting serum phosphorus on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment and thereafter as appropriate.

IF SERUM PHOSPHORUS IS WITHIN THE NORMAL RANGE:

Continue treatment with the same dose.

IF SERUM PHOSPHORUS IS BELOW THE NORMAL RANGE:

Increase dose† stepwise up to a maximum dose of 2 mg/kg administered every 2 weeks, as per the table that follows.

- Dose should not be adjusted more frequently than every 4 weeks.
- For patients who do not reach a serum phosphorus greater than the lower limit of the normal range, consider dividing total dose administered every 4 weeks and administering every 2 weeks.

	1st dose increase‡	2nd dose increase‡	3rd dose increase‡	4th dose increase	5th dose increase (max. dose)
If serum phosphorus 2 weeks post-dose adjustment is below lower limit of normal	1 mg/kg every 4 weeks OR 0.5 mg/kg every 2 weeks	1.5 mg/kg every 4 weeks§ OR 0.75 mg/kg every 2 weeks	2 mg/kg every 4 weeks§ OR 1 mg/kg every 2 weeks	1.5 mg/kg every 2 weeks	2 mg/kg every 2 weeks

Adapted from the CRYSVITA Product Monograph.[1]

IF SERUM PHOSPHORUS IS ABOVE THE NORMAL RANGE:

Withhold the next dose and reassess the serum phosphorus level in 4 weeks. The patient must have serum phosphorus below the normal range to be able to reinitiate CRYSVITA.

Once serum phosphorus is below the normal range, **restart CRYSVITA at approximately half the initial starting dose administered every 2 weeks**.

Reassess serum phosphorus **2 weeks after the dose adjustment**. If the level remains below the normal range after the re-initiation dose, the dose can be adjusted.

IF THE PATIENT UNDERGOES TREATMENT OF THE UNDERLYING TUMOUR (EXCISION OR RADIATION)

Interrupt treatment with CRYSVITA and reassess the serum phosphorus level after treatment of the tumour has been completed.

If serum phosphorus remains below the normal range, restart CRYSVITA at the patient's starting dose.

TIO=tumour-induced osteomalacia.
* See CRYSVITA Product Monograph for complete dosing and administration instructions.
† Rounded to the nearest 10 mg.
‡ For those individuals not reaching a serum phosphorus greater than the lower limit of the normal range, physicians may consider dividing total dose administered every 4 weeks and administering every 2 weeks.
§ In patients with high body weight, if the calculated dose is greater than 180 mg every 4 weeks, move to a divided dose every 2 weeks.

ADMINISTRATION GUIDANCE[1]

- Rotate injection sites: Administer at a different anatomic location (upper arms, upper thighs, buttocks, or abdomen) than the previous injection.
- Do not inject into moles, scars, or areas where the skin is tender, bruised, red, hard, or not intact.
- If a given dose requires multiple vials of CRYSVITA, contents from two vials can be combined for injection (the maximum volume per injection is 1.5 mL).
  - If multiple injections are required, administer at different injection sites.
- Monitor for signs of reactions.
- Visually inspect CRYSVITA prior to administration. CRYSVITA is clear to slightly opalescent, and colourless to pale brown-yellow. Do not use if the solution is discoloured or cloudy or if the solution contains any particles or foreign particulate matter.

IF A PATIENT MISSES A DOSE[1]

- Resume CRYSVITA as soon as possible at the prescribed dose and begin the new dosing schedule based on the date that dosing was resumed.
- To avoid missed doses, treatments may be administered 3 days either side of the scheduled treatment date.

Scan the QR code to enrol your patients in the Kyowa Kirin Cares™ Patient Support Program today!

If you have any questions, call us at 1-833-KYOWA-CA (1-833-596-9222).

Please consult the CRYSVITA Product Monograph at https://www.kkna.kyowakirin.com/wp-content/uploads/Crysvita-PM-English.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, drug interactions, dosing and administration, and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-590-9508.

Reference: 1. CRYSVITA (burosumab injection) Product Monograph. Kyowa Kirin Inc.

CRYSVITA® burosumab injection

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REVIEWED BY PAAB

KYOWA KIRIN